

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

REC'D 05 MAY 2006

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2005/001077

International filing date (day/month/year)
03.02.2005

Priority date (day/month/year)
04.02.2004

International Patent Classification (IPC) or both national classification and IPC
INV. C07D401/04 A61K31/505 A61P35/02

Applicant
NOVARTIS AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of
this opinion

see form
PCT/ISA/210

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2005/001077

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2005/001077

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-7
	No: Claims	
Inventive step (IS)	Yes: Claims	1-7
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-7
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)
and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)
see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents:

- D1: WO 03/066613 A (NOVARTIS AG; NOVARTIS PHARMA GMBH; LOISELEUR, OLIVIER; KAUFMANN, DANIE) 14 August 2003 (2003-08-14)
- D2: EP-A-0 564 409 (CIBA-GEIGY AG; NOVARTIS AG; NOVARTIS-ERFINDUNGEN VERWALTUNGSGESELLSCHA) 6 October 1993 (1993-10-06)
- D3: WO 99/03854 A (NOVARTIS AG; NOVARTIS-ERFINDUNGEN VERWALTUNGSGESELLSCHAFT MBH; ZIMMERM) 28 January 1999 (1999-01-28) cited in the application
- D4: US-A-5 521 184 (ZIMMERMANN ET AL) 28 May 1996 (1996-05-28) cited in the application
- D5: WO 2004/074502 A (CIPLA LTD; KANKAN, RAJENDRA, NARAYANRAO; RAO, DHARMARAJ, RAMACHANDRA;) 2 September 2004 (2004-09-02)
- D6: WO 03/077892 A (NOVARTIS AG; THE UNIVERSITY OF MELBOURNE; GILBERT, RICHARD, ERNEST; KE) 25 September 2003 (2003-09-25)
- D7: WO 02/22597 A (NOVARTIS AG; NOVARTIS-ERFINDUNGEN VERWALTUNGSGESELLSCHAFT M.B.H; BUERG) 21 March 2002 (2002-03-21)

2. Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-7 is not new in the sense of Article 33(2) PCT.

Document D1 discloses imatinib compounds in a salt form (see page 14, second paragraph). A list of specific preferred salts are disclosed on page 2, last paragraph.

The skilled person, by combining these 2 technical teachings, would in a clear and unambiguous manner, obtain the claimed salts of this application.

The same goes for document D2 (see example 19 and the list of salts on page 3, lines 31-44).

3. Inventive step

In case the applicant amends the claims in order to restore novelty, then these novel salts would be considered as a invention selection from a broader family of salts as disclosed in D1 and D2.

Such a selection can only be regarded as inventive, if the claimed salts presents unexpected effects or properties in relation to the rest of the family.

However, no such effects or properties are indicated in the application. Hence, no inventive step could be acknowledged for any novel specific salts.

Re Item VI

Certain documents cited

Document D5 is cited as P category in the search report, in the european phase this document would become relevant regarding novelty of the claimed subject matter when the salt is HCl.

Re Item VII

Certain defects in the international application

Contrary to the requirements of Rule 5.1 (a)(ii) PCT, the relevant background art disclosed in the documents D1, D2 and D5 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application

In case this application is proceeded in a european phase, then we draw the attention of the applicant that according Rule 29 EPC, independent claims 2,3,4,5 should be linked to claim 1.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2005/001077